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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,597	02/15/2002	Roy Sanders	2880/360	9386
23838	7590	12/17/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			ROBERT, EDUARDO C	
			ART UNIT	PAPER NUMBER
			3732	
DATE MAILED: 12/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/075,597	SANDERS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Eduardo C. Robert	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 September 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10-13 and 16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 9, 14 and 15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 2/15/02 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

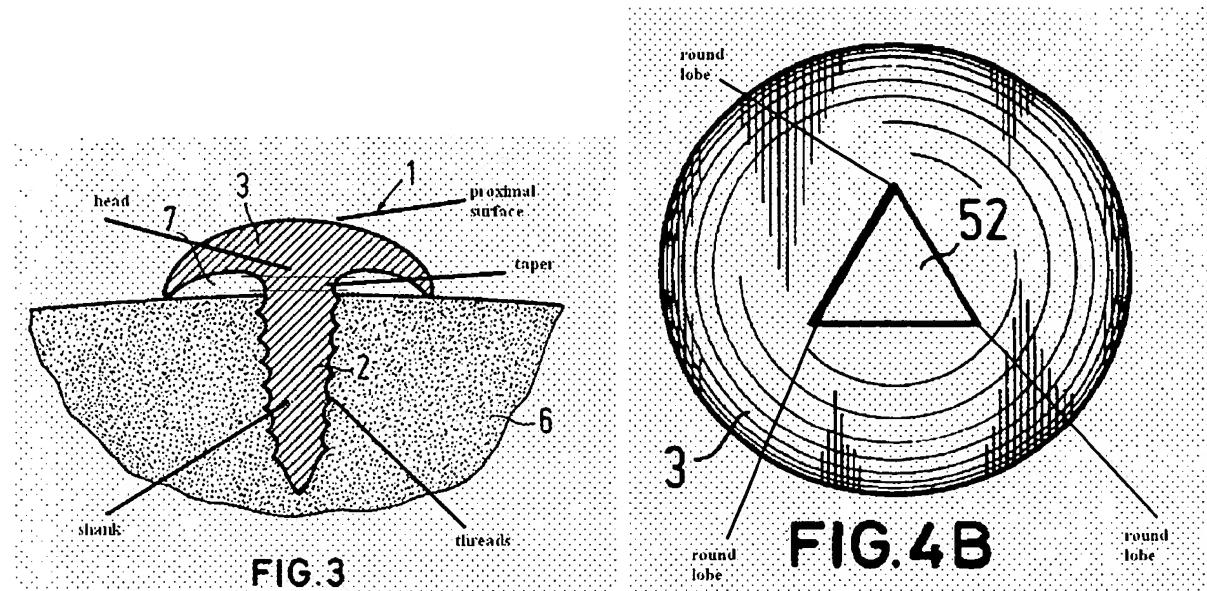
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (U.S. Patent 6,015,410).

Tormala et al. disclose a surgical screw which is bioabsorbable in vivo and comprises an elongated shank with threads, a head perpendicular to a longitudinal axis of the shank, and the shank protruding from the head (see Figure 3 below). The head comprises a recess 52 in the proximal surface and the recess has a cross-section with a rotational symmetry around the longitudinal axis of the shank and wherein the recess has an odd number of rounded lobes, i.e. 3, extending away from the center of the head. It is noted that Figure 4b (see Figure 4b below) shows corners of the triangle with some degree of roundishness and this roundishness could be formed by a circle or oval located upon the triangle corners. The screw comprises self-reinforced material (see col. 7, lines 20-23). The head has a distal surface that tapers toward the shank (see Figure 3 above). With regard to claim 3, it is noted that the screw of Tormala et al. is made by machining (see col. 7, lines 34-35) and this includes clearly the formation of the recess.



*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

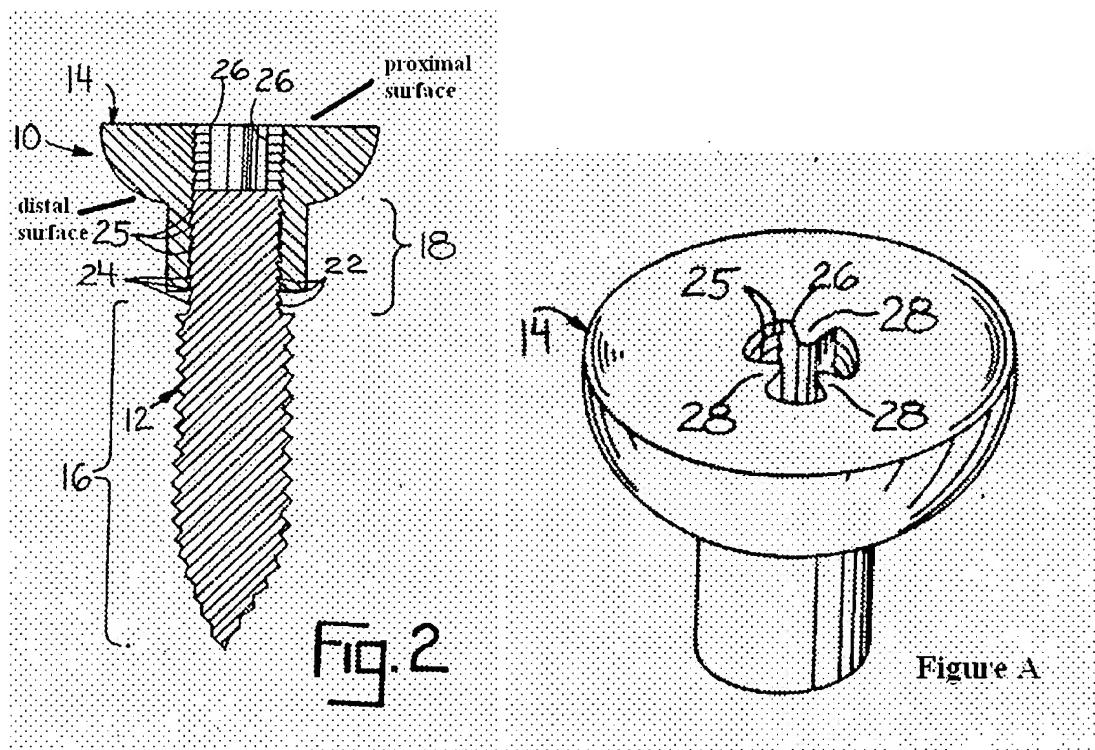
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodorek (U.S. Patent 5,167,664) in view of Fallin (U.S. Patent 6,666,868).

Hodorek discloses a bone screw comprising an elongated shank 12 with threads, a head 14 having a proximal surface perpendicular to a longitudinal axis of the shank, and the shank protrudes from the head (see Figure 2 below). The whole bone screw, i.e. the combination of all elements, can be considered one-piece since the several parts which are rigidly secured together as a single unit or piece. Therefore, the constituent parts are so combined as to constitute a

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unitary whole or structure. In re Larson, 144 USPQ 347 (CCPA 1965). The head comprises a recess, e.g. 26, having a cross-section with a rotational symmetry around the longitudinal axis and wherein the recess includes an odd number of rounded lobes extending away from the center of the head (see Figure A below). It is noted that the lobes are formed from ovals located on the recess, thus forming a cloverleaf shape (see Figure A below). The head has a distal surface which tapers toward the shank (see Figure 2 below). Hodorek further discloses an inserter which is used with the recess of the head 14 (see col. 2, lines 34-37). Hodorek discloses the claimed invention except for screw being made from a bioabsorbable material.



Fallin teaches to construct bone screws of bioabsorbable material so that problems such as the screw being palpable under the skin or interference with certain types of diagnostic imaging are solved (see col. 1, lines 37-47). Hodorek also discloses that making bone screws of

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other material is well known in the art and within the skills of one skill in the art (see col. 5, lines 54, through col. 6, line 3). It would have been obvious to one skill in the art at the time the invention was made to construct the bone screw of Hodorek made from a bioabsorbable material in view of Fallin, in order to prevent problems such as the screw being palpable under the skin or interference with certain types of diagnostic imaging. Moreover, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. With regard to claim 3, it is noted that the device of the combination of Hodorek as modified by Fallin appears to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone screw of the combination of Hodorek as modified by Fallin from self-reinforced biodegradable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodorek (U.S. Patent 5,167,664) in view of Fallin (U.S. Patent 6,666,868) as applied to claim 14 above, and further in view of Hemer (U.S. Patent 5,019,080).

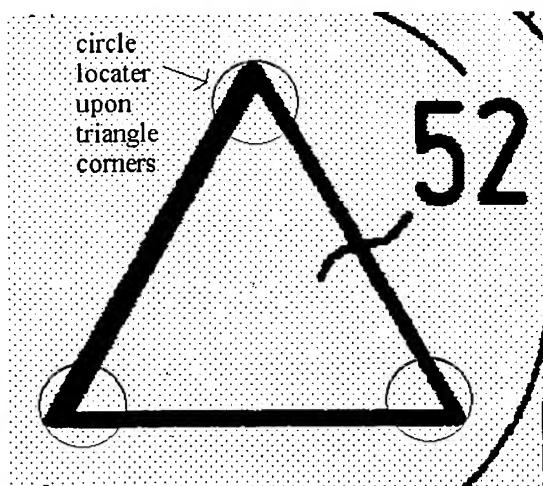
The combination of Hodorek and Fallin discloses the claimed invention except for the distal end of the inserter being progressively smaller towards the distal tip of the distal end. Hemer teaches to construct a distal end of an inserter 20 being progressively smaller toward a

distal tip of the distal end in order to prevent possible wobbling of the screw when driven by the inserter (see Figure 1 and col. 4, lines 25-33, col. 5, lines 1-6, col. 3, lines 1-3, and 31-35). It would have been obvious to one skill in the art at the time the invention was made to construct the screw of the combination of Hodorek as modified by Fallin with the inserted distal end being progressively smaller towards the distal tip of the distal end in view of Hemer, in order to prevent wobbling of the screw when it is driven by the inserter.

#### *Response to Arguments*

Applicant's arguments filed on September 29, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that Tormala does not disclose or suggest recess with rounded lobes, it is noted that, as explained in the rejection above, Tormala shows corners of the triangle with some degree of roundishness and this roundishness could be formed or be part of a circle or oval located upon the triangle corners. The examiner has included a drawing below showing how the corners roundishenss are considered.



In response to applicant's argument that Hodorek does not disclose a one-piece screw, it is noted that the elements which form the screw of Hodorek are secured together as a single unit or piece. Therefore, the constituent parts are so combined as to constitute a unitary whole or structure. *In re Larson*, 144 USPQ 347 (CCPA 1965).

***Conclusion***

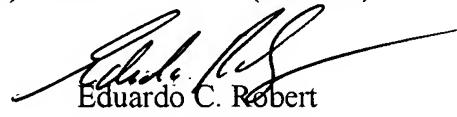
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.